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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/825,430 | 04/16/2004 | Hirokazu Sakai | 252010US0 | 9934 |
| 22850 | 7590 | 05/15/2009 | | |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | | |
| EXAMINER | | | | |
| VENKAT, JYOTHSNA A | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1619 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 05/15/2009 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/825,430

Applicant(s)

SAKAI ET AL.

Examiner

JYOTHSNA A. VENKAT

Art Unit

1619

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-12, 14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-12, 14 and 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of amendment and remarks filed on 2/17/09. Claims 13 and 15 have been canceled and claim 21 has been added as per applicants' amendment dated 2/17/09.

Status of claims

Claim 9 is withdrawn from consideration as being drawn to non-elected subject matter (election with traverse dated 11/29/07). **Claims 13 and 15 are cancelled.** Claims 1-8, 10-12, 14 and 16-21 are currently examined in the application.

Generic claims are examined to the extent that it reads on the elected species formula (1) under amphipathic amide lipid (component (A)) and ethylene glycol stearate under component (B).

Claim Rejections - 35 USC § 103

Claims 1-8 and 10-12, 14, and 16-21 are rejected under 35 U.S.C. 103(a) as being obvious over the combination of EP 1,166,766 ('766) and U. S. patent 5,876,705 ('705).

The instant application is claiming hair cleansing composition comprising:

- 1. Amphipathic amide lipid of formula 1*
- 2. compound belonging to B(species is ethylene glycol distearate)*
- 2. surfactant*
- 3. cationic polymer*

EP '766 teaches external preparation compositions. See the abstract, and see page 2, formula I for ingredient I claimed. see also pages 3-5 for the amide lipids, which are species belonging to formula I (Ingredient 1). EP '766 at paragraph 22 teaches adding surfactants to compositions. The weight percent of the surfactant is 0.01-20% and the weight percent of amide

lipid 0.001-50%. EP '766 at paragraph 24 teaches hair care applications and this includes shampoo. EP under this paragraph suggests adding components ordinarily employed in hair cosmetics. Examples 3-4 are drawn to hair formulations. The difference between EP and the instant application is EP does not teach claimed species belonging to B and cationic polymer.

Patent '705 teaches conditioning shampoo compositions. See the abstract; see col.2, ll 25-30 for anionic, amphoteric and non-ionic surfactant. See col.s 4-5 and col.6, ll 1-34 for anionic surfactant. See col.6, ll 35-68 and col.s 7-8 and col.9, ll 1-6 for amphoteric surfactant, see col.9, ll 8-68 and col.10, ll 1-14 for non ionic surfactant, see col. 17, line 7 through col.19, line 27 for cationic polymers. Patent at col.2, ll 35-39 teaches conditioning agents and these can be silicones or cationic surfactant or cationic polymers. see col.19, ll 5-20 for claimed cationic cellulose and cationic guar gum. See paragraph bridging col.s 21-22 for suspending agents. Preferred suspending agent is claimed species(see col.21, ll 60-65). See also examples VI-X for ethylene glycol distearate, cationic polymer, which is polyquaternium 10 and surfactant.

Accordingly it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the compositions of EP '7669 and combine with agents that are conventionally used in hair care like surfactants , cationic polymers and suspending agents taught by patent '705 expecting beneficial effect to hair. One of ordinary skill in the art would be motivated to add the ingredients of '705 with the reasonable expectation of success that the compositions which has the diamide provide moisturizing feel and silkiness to the hair and adding cationic polymers provide conditioning property to the hair and adding surfactant provide cleansing actions. Thus the compositions not only cleanse the hair but also provide moisturizing and conditioning properties to the hair. This is a prima facie case of obviousness.

Response to Arguments

Applicant's arguments filed 2/17/09 have been fully considered but they are not persuasive.

Applicants' argue:

“Applicants respectfully submit that it would not have been obvious to include components (A) and (B) in a hair cosmetic composition in a ratio of 5:1 to 1 : 1,000 as the cited art does not disclose any relationship between the two components.

As noted previously, Uchiyama et al. describe that ethylene glycol stearate is a dispersant for a silicone hair conditioning agent. The dermatologic preparation of Hoshino et al. fails to disclose a silicone hair conditioning agent. Thus, there would be no motivation to add the dispersant for a silicone hair conditioning agent of Uchiyama et al. into the dermatologic preparation of Hoshino et al. as suggest in the official action, at an (A):(B) ratio of 5:1 to 1:1,000, as Hoshino et al.'s composition does not contain a silicone hair conditioning agent. Where is the motivation to have a ratio of amphipathic amide lipid to dispersant for a silicone hair conditioning agent of 5:1 to 1 : 1,000 in a composition which does not contain a silicone hair conditioning agent? There would be no motivation to have a relative ratio of components when the motivation of including a dispersant for a silicone hair conditioning agent is not present. Accordingly, the claimed invention in which the amphipathic amide lipid

and component (B) are present in a ratio of 5:1 to 1 : 1,000 would not have been obvious. Withdrawal of the rejection under 35 U.S.C. 103(a) is respectfully requested”.

I Admitted by examiner EP '766 does not teach the claimed component B which is taught by patent '705 as a dispersant. Patent '705 teaches the addition of dispersant to assist with dispersion of silicone hair conditioning agent. EP teaches claimed amphipathic amide lipid. The lipid claimed and taught by EP and the silicone hair conditioning agent taught by patent '705 are both drawn to oily substances (emphasis added). One of ordinary skill in the hair care art would use the dispersant of patent '705 into the compositions of EP '766 so that the same dispersant can also assist with the dispersion of amphipathic amide lipid. Applicants' attention is drawn to page 3, ll 20-21 of instant specification, where the specification teaches the addition of component B improves the dispersion stability of component A .

EP teaches the weight percent of the amphipathic lipid being 0.001-50% and Patent '705 teaches the weight percent of suspending agent being 0.1-to about 10%. The weight percent claimed in claim 14 for component (B) is within this weight percent and the weight percent claimed for amphipathic amide lipid (component (A) is within the weight percent taught by EP, therefore the ratio of components A:B claimed is met by the combination of both the references.

Applicants' also argue:

“Moreover, applicants observe an enhancement in hair penetration of the amphipathic amide lipid when combined with component (B). The examiner's attention is directed to Table 1 on page 29 of applicants' specification which evaluates the hair conditioning performance of the

claimed combination of components (A) and (B) as compared with compositions lacking component (B) (comparative example 1) or lacking component (A) (comparative example 2). For the examiner's convenience a portion of the data is reproduced below:

Table 1

| | | Examples | | | (Unit of content is Comparative Example 1) |
|--|---|----------|---------|---------|---|
| | | 1 | 2 | 3 | 1 |
| (A) | Amphipathic amide lipid A | 0.5 | - | 0.5 | - |
| | Amphipathic amide lipid B | - | 0.1 | - | 2 |
| (B) | Ethylene glycol distearyl ester | 2 | - | - | - |
| | Distearyl ether | - | 2 | 2 | - |
| Others | Sodium polyoxyethylene (2) lauryl ether sulfate | 10 | 10 | 10 | 10 |
| | Sodium lauryl sulfate | 5 | 5 | 5 | 5 |
| | Cocoyl monoethanolamide | 0.5 | 0.5 | 0.5 | 0.5 |
| | Cationic hydroxyethylcellulose | 0.3 | 0.3 | 0.3 | 0.3 |
| | Cationic guar gum | 0.5 | 0.5 | 0.5 | 0.5 |
| | 50 wt % aq. NaOH soln/50 wt % citric acid | q.s.* | q.s.* | q.s.* | q.s.* |
| | Purified water | Balance | Balance | Balance | Balance |
| pH | | 3.5 | 3.5 | 3 | 3.5 |
| Buffering capacity (NaOH-gram equivalent/l.) | | 0.02 | 0.01 | 0.01 | 0.01 |
| Evaluation | Resilience and strength of hair | 3.1 | 2.7 | 3.9 | 1.8 |
| | Smoothness of hair | 3.8 | 3.6 | 3.8 | 2.1 |
| | Moist feeling of hair | 3.8 | 3.7 | 3.8 | 2.2 |
| | Storage stability (50°C x 1 month) | A | A | A | C |

*: amount enough for pH adjustment

"Example 1 containing an amphipathic amide lipid and ethylene glycol distearyl ester exhibited high evaluation for hair conditioning performance in terms of resilience and strength of hair, smoothness of

hair and moist feeling of hair plus, no change in appearance upon storage at 50°C for one month.

In contrast, comparative example 1, having an amphipathic amide lipid but no ethylene glycol distearyl ester exhibited lower hair care performance and exhibited separation or gelation upon storage at 50°C for one month. Thus, through the combination of amphipathic amide lipid and component (B), applicants are able to observe an improved hair protecting effect and enhanced dispersion stability”.

In response to the above data , the test results in the specification are expected since component B taught by patent '705 as a dispersing agent would provide storage stability. See examples 1 vs comparative example 2. Example 1, drawn to instant invention had 2 % ethylene glycol distearyl ester, where as comparative example 2 had 1 % ethylene glycol distearyl ester. The test is not conducted under identical conditions and in spite of using lower weight percent for component B , the storage stability is still the same .

With respect to smoothness of hair and moist feeling, amphipathic lipid provide hair moisturizing properties and this is expected property.

With respect to resilience and strength of hair only amphipathic lipid A (component (A)) and ethylene glycol distearyl ester (component (B)) showed superior results than the combination of amphipathic lipid B (component (A)) and distearyl ether (component (B)) of example 2.

In conclusion the test results are expected because of amphipathic lipid and storage stability is expected in view of component B and the test results in the specification are not commensurate with the scope of claims.

In conclusion the claims are prima facie obvious within the meaning of 35 U. S. C. 013 over the combination of EP '766 and patent '705.

This application contains claim 9 drawn to an invention nonelected with traverse in the reply filed on 11/29/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30:1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JYOTHSNA A VENKAT /
Primary Examiner, Art Unit 1619